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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,598	03/29/2001	Thomas M. Jessell	57477-A-PCT-US/JPW/MVM	5690

7590 04/27/2006

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,598	JESSELL ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,38,45,48-50,52,60 and 126-130* is/are pending in the application.

4a) Of the above claim(s) *38,129 and 130* is/are withdrawn from consideration.

5)☒ Claim(s) *126* is/are allowed.

6)☒ Claim(s) *27,45,48-50,52,60,127 and 128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/04; 2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office Action is in response to the amendment filed May 13, 2004.

Claims 1-26, 28-37, 39-44, 46, 47, 51, 53-59, and 61-125 have been canceled. Claims 38, 129, and 130 has been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 27, 45, 48, 49, 50, 52, 60, and 126-128 are under examination.

Withdrawal of Rejections:

The rejection of Claims 27, 45, 48, 49, 50, 52, 60, 127, and 128 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

The rejection of Claims 27, 127, and 128 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn.

The rejection of Claims 27, 45, 48, 49, 50, 52, 60, 127, and 128 35 U.S.C. 112, first paragraph, because the specification, while being enabling for MNR2 comprising SEQ ID NO: 1, does not reasonably provide enablement for all MNR2, is withdrawn.

Maintenance of Rejections:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 49, 50, 52, and 60 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. These Claims are drawn to methods of treating neurological diseases/injuries by administering the MNR2 protein to a subject, thus causing differentiation of neuronal precursor cells. Simply, these methods are not art-recognized such that there could be a nexus between other prior art proteins and the treatment of neurological diseases/injury and MNR2.

In *Ex parte Forman* (230 USPQ 546) the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation:

1) Quantity of experimentation necessary: It would require undue experimentation to determine how one would treat diseases/injuries that are not known to be routinely treatable with a new protein that is involved with neuronal cell differentiation.

2) Amount of direction or guidance presented: Page 50+ provides a generic discussion of methods of treatment using protein, and these methods are not specific to neural abnormalities.

3) Presence or absence of working examples: None.

4) Nature of the invention; 5) State of the prior art; 6) Relative skill of those in the art: The invention is highly technical and the MNR2 protein is not recognized in the prior art. Those working in the art are highly skilled.

7) Predictability or unpredictability of the art: Finding a protein that is involved in the differentiation of neurons is highly unpredictable; using the protein to differentiate neuronal cells in vivo is highly unpredictable.

8) Breadth of the claims: The claims are very broad.

For all of these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

At page 17 of their response, Applicants urge that the methods do not recite a specific method of administration and that this method will vary with the particular type of pharmaceutical composition comprising the MNR2 protein. The issue isn't whether one could administer a protein to a subject, but whether that protein will be active *in vivo* to accomplish the methods claimed. The specification does not teach how one would administer the MNR2 protein to induce differentiation of neural progenitor cells into somatic motor neurons in a subject, treat a subject with abnormally associated functioning motor neurons, treat a subject with neurodegenerative diseases, treat a subject with acute nervous system injury, or treat a subject with neuromuscular disease because the MNR2 protein has not been administered *in vivo* and the art does not recognize MNR2 or similar proteins for use in these methods. There are no examples provided, and there is no analogous art to create a predictable nexus for the use of MNR2 in these methods. Thus, the methods claimed are not enabled.

New Rejection:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 45, 48, 49, 50, 52, 60, and 127-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 states that the fragment will have the biological activity of the MNR2 protein. The specific activity that the fragment is to have is not set forth in the claim, rendering the claim indefinite.

Claim 126 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0700.

Karen Cochrane Carlson Ph.D

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER